Congress of the United States
Washington, DC 20515

FOR IMMEDIATE RELEASE
June 30, 2005

Contact: Karen Lightfoot (202) 225-5051 (Waxman)
Tara McGuinness (202) 225-2836 (Markey)

REP. WAXMAN AND REP. MARKEY PUSH FOR PUBLIC ACCESS TO MEDICAL INFORMATION

Lawmakers' legislation will preserve a robust system of research and disclosure

WASHINGTON, DC – Today Representatives Henry A. Waxman (D-CA) and Edward J. Markey (D-MA), two senior members of the Energy and Commerce Committee, along with 30 other members of the House introduced the Fair Access to Clinical Trials (FACT) Act. This legislation will ensure that patients, clinicians and the public have access to basic clinical trial information about drugs, biologics, and medical devices. Recent news reports have indicated that some pharmaceutical companies are not releasing clinical trial information that raises concerns about their drugs or devices. The lack of mandated full disclosure allows companies to paint a distorted picture of the safety and effectiveness of drugs and medical devices by selectively disclosing trial information.

"We cannot continue to allow companies to promote only the positive results of clinical studies and suppress the negative results," Rep. Waxman said. "The present system can seriously mislead physicians and pose safety hazards for patients. The Fair Access to Clinical Trials Act creates a publicly accessible clinical trials database and requires that study sponsors use it."

"Drug companies should not be able to pick and choose which trials they want to disclose and which they want to hide from the public," said Rep. Markey. "The medical community deserves to have a complete picture of the safety and effectiveness of drugs and devices."

The "Fair Access to Clinical Trials Act" would establish a mandatory federal clinical trials database. This legislation would:

- Require sponsors of privately and publicly funded studies of drugs, biologics, or medical devices to register using a database that builds on the National Library of Medicine's www.clinicaltrials.gov;
- Provide public access to basic information on studies before they begin, such as the disease or condition with which the trial is concerned, the hypothesis being tested, the sponsor and principal investigator, and the sources of funding;
- Provide public access to the results of clinical studies, including primary and secondary outcomes and significant adverse events; and
- Authorize the Secretary of HHS to impose penalties for noncompliance, including revoking a sponsor's eligibility for further federal funding and imposing civil money penalties.

This Bill has been endorsed by: The Pediatric AIDS Foundation, The National Breast Cancer Coalition Fund, American Medical Students Association, American Psychiatric Association, American Academy of Child and Adolescent Psychiatry, Consumers Union, Massachusetts Medical Society, Clinical Social Work Federation, and US PIRG.

For more information or a bill summary, please visit: http://www.waxman.house.gov/ or http://www.house.gov/markey/healthgen.htm

###